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FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007				
			EXAMINER BOWERS, NATHAN ANDREW	
			ART UNIT 1744	PAPER NUMBER

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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/727,037	Applicant(s) BROWN ET AL.	
	Examiner Nathan A. Bowers	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

1-32

- 4) ☒ Claim(s) ~~1-14, 25-30 and 32~~ is/are pending in the application.
- 4a) Of the above claim(s) 15-21, 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-14, 25, 27-30 and 32 is/are rejected.
- 7) ☒ Claim(s) 7 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>020905</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of claims 1-14, 25-30 and 32 in the reply filed on 15 March 2006 is acknowledged.

Claim Objections

Claims 26-30 are objected to because of the following informalities: method claims 26-30 are currently dependent upon apparatus claim 22. It is understood that claims 26-30 should be dependent upon claim 25. Appropriate correction is required.

Claims 14 and 28 contain the trademark/trade name IsoCode. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe an absorbent material and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, it is unclear if the swab defines the stabilized reagent chamber, or if the swab and the chamber are separately positioned on the handle at different locations. Claim 1 discloses "a handle having a chamber" and that "the swab includes a stabilized reagent in the chamber." Therefore, it is unclear whether or not the chamber is a part of the handle, the swab, or both. The structural relationship between handle, swab, and chamber is unclear from the claim language.

The term "whipping" in claim 26 is a relative term which renders the claim indefinite. The term "whipping" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This "whipping" action needs to be described in greater detail in the claims because a number of different types of mixing actions can be described as "whipping." Therefore, one of ordinary skill in the art would not clearly understand if this whipping action is meant to be synonymous with, for example, stirring, rotating or shaking. The term "whipping" does not clearly define the boundaries of the claimed invention, and therefore makes the claim unsuitable for prosecution and litigation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1, 2, 5, 6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Schramm (US 5935864).

With respect to claim 1, Schramm discloses an apparatus for preparing samples for analysis comprising a handle having a swab (Figure 7:39) attached at the end of the handle. The swab includes a chamber within which a stabilized reagent is placed. A sample tube (Figure 7:37) extends from an end of the chamber. The apparatus further includes a wand assembly (Figure 7:43) that comprises a buffer container at one end of the assembly, and a stand at another end of the assembly. Figures 7-9 indicate that the wand assembly is generally in the shape of a cylinder shaft, and that both ends of the assembly are planar and therefore capable of being used as a stand. Column 4, line 43 to column 5, line 29 indicates that the handle is configured to be attached to the wand assembly in order to analyze a sample that has been collected on the swab. Schramm teaches that the apparatus is designed for testing biological samples such as blood, however does not indicate exactly what types of buffers and reagents are used.

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Schramm's invention is inherently capable for use in PCR analysis provided that the appropriate buffers and reagents are loaded within the disclosed apparatus.

With respect to claim 2, Schramm discloses the apparatus in claim 1, wherein the buffer container includes a film (Figure 7:44) covering one end of the container. This is disclosed in column 4, lines 55-59.

With respect to claim 5, Schramm discloses the apparatus in claim 1, wherein the handle removably attaches to the wand assembly by inserting the swab into the shaft of the wand assembly. Column 4, lines 55-59 teach that the swab is pushed through the film covering the container, and that the swab is inserted into the shaft of the wand assembly in this manner.

With respect to claim 6, Schramm discloses the apparatus in claim 5, wherein a cover of the handle is configured to detach from the swab when the swab is attached to the wand assembly. Figures 7-9 indicate that the sample tube (Figure 7:37) comprises a cover, and can be removed from the swab assembly (Figure 7:39) when the swab is mated to the wand assembly.

With respect to claim 9, Schramm discloses the apparatus in claim 1, wherein the handle and wand assembly are configured to be portable. This is apparent from Figure 3, which shows the apparatus in proportion to a person's hand. Furthermore, all of the necessary reagents and buffers are entirely contained within the apparatus, thus inherently contributing to its portability.

2) Claims 1, 2, 5 and 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by DiCesare (US 20020001539).

With respect to claim 1, DiCesare discloses an apparatus for preparing samples comprising a handle (Figure 4:17) having a chamber (Figure 4:23). A swab (Figure 5:27) is attached to an end of the handle, and the chamber includes a reagent. This is disclosed in paragraph [0065]. Furthermore, a sample tube (Figure 4:40) is positioned coaxially around the chamber in such a way that the sample tube extends from both ends of the chamber. A wand assembly (Figure 4:55) is provided, and includes a container (Figure 5:36) at an end of a shaft and a stand at another end of the shaft. Although DiCesare does not expressly disclose that the chamber holds a buffer, it inherently could because a fluid tight boundary is formed by the chamber walls and first and second seals (Figure 4:49, 50). Figures 4 and 5 indicate that the wand assembly is generally in the shape of a cylinder shaft, and that both ends of the assembly comprise flat surfaces, and therefore are capable of being used as stands. Paragraphs [0058]-[0066] indicate that the handle is configured to be attached to the wand assembly. Although DiCesare suggests that the invention is used for microorganism detection, it inherently could be used for PCR analysis provided that the appropriate buffers and reagents are loaded within the disclosed apparatus.

With respect to claim 2, DiCesare discloses the apparatus in claim 1 wherein the buffer container (Figure 5:36) includes a film (Figure 4:49, 50) covering one end of the container. This is disclosed in paragraph [0065].

With respect to claim 5, DiCesare discloses the apparatus in claim 1 wherein the handle removably attaches to the wand assembly by inserting the swab into the shaft of the wand assembly. This is apparent from Figure 5.

With respect to claims 8 and 9, DiCesare discloses the apparatus in claim 1 wherein the stand is configured to attach to a slot in a hand-held detector for biological materials. Paragraphs [0057] and [0075] indicate that the wand assembly is inserted into the sample port of a portable device. It is apparent from Figure 10 that the lid (Figure 10:22) of the device is configured to produce a conformal seal with the wand assembly stand.

With respect to claim 10, DiCesare discloses the apparatus in claim 1 wherein an absorbent material is attached at an end of the swab. In paragraph [0035], DiCesare describes the swab as being an absorbent polymeric material.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3) Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm (US 5935864).

Schramm discloses the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 102 rejection above. In addition, Schramm discloses in column 4, lines 49-51

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that the chamber includes a vent (Figure 7:41). Schramm, however, does not indicate that the chamber includes a plurality of vents. Regardless, it would have been obvious to include multiple vents if it is known that the single vent is unable to effectively disperse air that is displaced by the buffer solution. In this way, one would avoid the build up of excess pressure. In general, the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

4) Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm (US 5935864) as applied to claim 1, and further in view of Wickstead (US 6634243).

With respect to claim 3, Schramm discloses the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 102 rejection above, however does not expressly disclose that the wand assembly further comprises a spike to rupture the buffer container.

Wickstead discloses an apparatus for preparing samples that comprises a buffer chamber (Figure 1:10) and a sample container (Figure 1:20). The buffer chamber and sample container are able to fit inside a handle (Figure 1:50) comprising a reagent test strip (Figure 1:40). This is disclosed in column 4, line 39 to column 5, line 40 and column 7, lines 28-30. The sample container includes a spike (Figure 7:24) that is capable of rupturing a membrane (Figure 1:18) on the buffer chamber in such a way to allow the buffer to exit the container.

Schramm and Wickstead are analogous art because they are from the same field of endeavor regarding sample preparation apparatuses.

At the time of the invention, it would have been obvious to equip the wand assembly proposed by Schramm with a spike capable of rupturing the frangible membrane on the buffer container when the handle is connected with the wand assembly. This would have been beneficial because one would no longer need to use the swab itself to break the frangible membrane. Since directly contacting the swab to the membrane might lead to sample contamination or damage to the swab, it would have been advantageous to provide the wand assembly with a separate spike that is activated when the handle is mated with the wand assembly.

5) Claims 10, 25, 27 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm (US 5935864) as applied to claim 1, and further in view of DiCesare (US 20020001539).

Schramm discloses the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 102 rejection above. Schramm also discloses a corresponding method in which the apparatus is used to analyze a biological sample. The swab is wiped over a test surface, and is brought into contact with the wand assembly. A buffer container in the wand assembly is ruptured in order to enable buffer to flow over the swab and into a chamber for mixing with a reagent. Schramm, however, does not expressly indicate that the swab comprises an absorbent material.

DiCesare discloses the apparatus as previously described. In paragraphs [0013]-[0024], DiCesare indicates that the use of absorbent swabs to collect biochemical analytes is well known in the art.

Schramm and DiCesare are analogous art because they are from the same field of endeavor regarding sample preparation devices.

At the time of the invention, it would have been obvious to supply Schramm's apparatus with an absorbent material at the end of the disclosed swab. Absorbent swabs are known in the art to effectively collect a variety of biological materials. The use of absorbent materials in Schramm's device would be beneficial because absorbent materials would be able to effectively move the sample to the reagent chamber through the addition of a buffer and a subsequent wicking action. This is described by DiCesare in paragraph [0024]. DiCesare further indicates in paragraph [0020] that absorbent materials are favored in the art because a number of solutions and reagents can be applied to them to facilitate the initial collection of samples.

6) Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm (US 5935864) in view of DiCesare (US 20020001539) as applied to claim 10, and further in view of Mennen (US 4562043).

Schramm and DiCesare disclose the apparatus set forth in claim 10 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose that the absorbent material is held in place by a retaining ring.

Mennen discloses an apparatus for preparing a sample for analysis. The apparatus comprises a swab (Figure 1:22) made from an absorbent material, and a chamber (Figure 1:24) that contains a reagent. The absorbent swab is attached to the apparatus through a heat sealing method that produces an indented area (Figure 7:20)

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that acts as a retaining ring. This is disclosed in column 7, line 65 to column 8, line 21.

The absorbent swab is used for collecting a variety of different biological samples.

Schramm, DiCesare and Mennen are analogous art because they are from the same field of endeavor regarding sample preparation devices.

At the time of the invention, it would have been beneficial to attach the absorbent material to the end of the swab disclosed by Schramm and DiCesare using a retaining ring. The use of a retaining ring would ensure that the swab is not dislodged from the apparatus during sample collection, and therefore would make the apparatus less susceptible to damage.

7) Claims 12, 13, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm (US 5935864) in view of DiCesare (US 20020001539) as applied to claims 10 and 25, and further in view of Berke (US 5084045).

Schramm and DiCesare disclose the apparatus and method set forth in claims 10 and 25 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose positioning a mesh cover underneath and above the absorbent material.

Berke discloses an apparatus and method for preparing samples for analysis. Biological specimens are collected upon a swab (Figure 3:58) and transferred to a reaction area (Figure 1:42, 44). This is disclosed in column 9, line 39 to column 10, line 42. Column 10, lines 43-57 indicate that a filter (Figure 1:52) is positioned between the swab and the reaction area so that biological analytes collected by the swab are allowed to pass through to the reaction area, but solid swab particles are not.

Schramm, DiCesare and Berke are analogous art because they are from the same field of endeavor regarding sample preparation devices.

At the time of the invention, it would have been obvious to position a filter/mesh material on both sides of the absorptive swab disclosed by Schramm and DiCesare. This would have been beneficial because the mesh would have securely supported the absorptive swab material on the handle, and would have ensured that it would not be broken or damaged during sample collection. The mesh would have also been advantageous because it would not have interfered with the transfer of the buffer from the wand assembly, through the absorptive material, and into the reagent chamber.

8) Claims 14 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm (US 5935864) in view of DiCesare (US 20020001539) as applied to claims 10 and 25, and further in view of Sangha (US 20030113906).

Schramm and DiCesare disclose the apparatus and method set forth in claims 10 and 25 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose the use of IsoCode paper as the absorbent material.

Sangha discloses an apparatus for collecting biological samples from a surface that comprises swap composed of an absorbent material (Figure 1:20). In paragraph [0036], Sangha teaches that IsoCode paper is suitable for use as this type of collection substrate.

Schramm, DiCesare and Sangha are analogous art because they are from the same field of endeavor regarding device for the collection of biological samples.

At the time of the invention, it would have been obvious to utilize IsoCode paper as the absorbent material within the apparatus disclosed by Schramm and DiCesare. In paragraph [0036], Sangha teaches that IsoCode paper can be manufactured to have a sticky or adhesive surface, which aids in the collection of biological samples. In paragraph [0042], Sangha states that IsoCode paper is also beneficial because it is versatile in its operation, since IsoCode paper can be used in both dry and wetted states to collect samples.

Allowable Subject Matter

Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 26 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 7 and 26 both include limitations regarding a wand assembly with an extendable grip. Claim 26 further involves "whipping" the apparatus after the grip on the wand is extended. The prior art does not disclose an apparatus for preparing samples that is designed to be "whipped" and includes all of the limitations set forth in claims 1 and 25. Since the purpose of the extendable grip is to facilitate "whipping," it is natural

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that this limitation is also not found in the prior art. The closest art is represented by Zhou (US 20040184966), which cannot be considered prior art due to its date. Zhou discloses a biological specimen collection device with a telescoping grip. The telescoping grip is connected to a sample collection swab and allows the user to access remote samples due to the extension of the grip. Even if Zhou was prior art, it could not be combined with Schramm or DiCesare because there is no motivation to add an extendable grip to the wand assembly. Zhou would only give motivation to add an extendable grip to Schramm and DiCesare's handle assemblies since the handle assemblies are connected to the swabs and are used for collecting samples.

References similar to Zhou that are prior art regarding extendable handle assemblies could not be used to reject claims 7 and 26 for the same reason.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 5, 9, 10, 12, 25, 27, 29 and 32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 12-17, 20, 26 and 34 of Application No. 10/852684. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application is generic to the Application No. 10/852684. Application No. 10/852684 includes limitations regarding a buffer container, a swab and a stabilized reagent chamber. The buffer container housing disclosed by Application No. 10/852684 is considered to be equivalent to the wand assembly disclosed in the instant application. Application No. 10/852684 states that the swab/reaction tube housing is configured to be attached to the buffer container housing. The instant application is deemed to be generic to Application No. 10/852684 because Application No. 10/852684 includes additional limitations regarding a plunger housing.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Silver (US 6328931), Karakawa (US 5543115), Igarashi (EP 1024354) and Skiffington (US 6180395) disclose the state of the art regarding sample collection devices.

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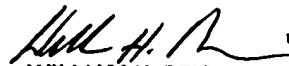
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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